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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,424	07/29/2003	Frieder Braunschweig	P10978.00	6026

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EXAMINER	
PATEL, NATASHA	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,424	BRAUNSCHWEIG ET AL	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on November 9, 2006 has been received and considered. By this amendment, Claims 1, 2, 4, 6, and 8 have been amended. Claims 1-14 are now pending in the application.

Claim Objections

2. In view of the Applicant's amendment to Claims 1, 2, and 4, the Examiner is withdrawing the claim objections that were made in the previous Office Action.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the monitoring/stimulating means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The Applicant's remarks concerning the Specification have been persuasive. Thus, the Examiner is withdrawing the objection that was made against the Specification in the last Office Action.

Claim Rejections - 35 USC § 112

6. Similarly, the Applicant's remarks concerning the 35 USC§112 rejections have been persuasive. Thus, the Examiner is withdrawing the 35 USC§112 rejections that were made against the Specification in the last Office Action.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

8. Claims 1-8 and 11-14 are rejected under 35 U.S.C. 103(a) as being obvious over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176).

9. Regarding Claim 1, Kieval discloses a system for collecting hemodynamic data from a patient (see col. 3, lines 42-44) and utilizing said data to optimize a cardiac pacing regimen for said patient (see col. 4, lines 10-13), comprising: a hemodynamic

monitor means (see absolute pressure sensor 160 and microcomputer 302) for continuously (see col. 16, line 21) collecting hemodynamic data (see col. 3, lines 42-44) of a patient and for storing said collected hemodynamic data (see RAM/ROM 310, 312, 314), a means for monitoring and/or stimulating cardiac tissue (see IPG 100) of a patient to provide or restore a desired cardiac rhythm (see col. 4, lines 40-43), and a means for integrating at least a portion of the collected hemodynamic data with the means for monitoring and/or stimulating cardiac tissue to optimize one or more hemodynamic characteristics of said patient (see col. 17, lines 34-54). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Furthermore, the examiner considers that the hemodynamic data (RVP signal) is integrated into the pulse generator's pacing program to establish an optimal AV delay (see col. 17, lines 25-29), which consequently optimizes a hemodynamic characteristic of the patient. Although Kieval mentions activity levels (see col. 10, lines 41-42) and periods of rest (see col. 10, line 64), Kieval does not explicitly disclose that hemodynamic data is collected during both activity and rest. However, Bornzin discloses a similar optimization system, in which the monitoring means (physiologic sensor 12) collects (see col. 7, lines 5-10) during periods of rest and periods wherein said patient is performing the activities of daily living (see col. 8, lines 61-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods of rest and during activity because Bornzin teaches the benefit of being able to

differentiate between activity and rest in order to provide an appropriate therapy (see col. 2, lines 26-39).

10. Regarding Claim 2, Kieval discloses that the hemodynamic monitor means is an absolute pressure sensor (see col. 8, lines 19-21) adapted to be fluidly coupled to a cardiac chamber of the patient (see Figure 4). The examiner considers that sensor 160 on lead 114 has the ability to be fluidly coupled. Furthermore, it has been held that the recitation that an element is "adapted to" perform function in not a positive limitation in any patentable sense (*In re Hutchinson*, 60 USPQ 138).

11. Regarding Claim 3, Kieval discloses that the means for monitoring and/or stimulating comprises a pulse generator (see col. 7, lines 54-55 and Figure 4).

12. Regarding Claims 5 and 14, Kieval discloses a method of optimizing hemodynamics of a patient (see col. 4, lines 10-13) having an implantable cardiac rhythm stimulation and monitoring device (see IPG circuit 300), comprising the steps of: collecting hemodynamic data from said patient (see col. 3, lines 42-44) with a hemodynamic monitor (see absolute pressure sensor 160 and microcomputer 302) adapted to be disposed in fluid contact with a volume of venous blood of said patient (see col. 5, lines 59-61). The examiner considers since the pressure sensor 160 is in the right ventricle and the venous blood enters the right ventricle, then the pressure sensor 160 is in fluid contact with the venous blood. Kieval discloses storing said collected hemodynamic data (see RAM/ROM 310, 312, 314). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Kieval further

discloses collecting cardiac event data from the patient (see col. 15, lines 40-46 and Figures 5 and 10) and storing the cardiac event data in a computer readable memory medium (see RAM/ROM 310, 312, 314). The examiner considers that although the ECG is stored in memory after it has already been processed, the ECG is still being stored in some way, shape, or form. Kieval discloses analyzing said hemodynamic data in conjunction with said cardiac event data to determine a cardiac stimulation sequence intended to optimize the hemodynamics of said patient, and providing said cardiac stimulation sequence to an implantable cardiac rhythm stimulation and/or monitoring device (see Kieval, col. 17, lines 34-54). Kieval does not disclose collecting hemodynamic data during activity levels above resting rate. Bornzin discloses performing this collection process during a period of time when a heart rate of the patient is elevated above a resting rate due to activity by said patient (see col. 9, lines 9-15 and col. 6, lines 6-14). The examiner considers the heart rate will inherently be higher during physical activity compared to the heart rate during rest. It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods activity because a patient will not always be at rest and Bornzin teaches the benefit of being able to provide an appropriate therapy at any activity level (see col. 5, lines 26-30).

13. Regarding Claim 6, Kieval discloses that the hemodynamic data is a pressure signal sensed in the right ventricle (see col. 3, lines 42-44).

14. Regarding Claim 7, Kieval discloses that the hemodynamic data is collected at a pre-determined time of day and at a pre-determined interval (see col. 17, lines 34-38

and lines 66-67). The examiner considers since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day, hemodynamic data is also collected at pre-determined times of the day.

15. Regarding Claim 8, Kieval discloses that during the providing step an A-V interval (see col. 17, lines 52-54) comprises a part of the cardiac stimulation sequence. The examiner considers that the main goal of the AV optimization method is to provide an optimized AV interval to the cardiac pacing regime so an AV interval must be provided to the cardiac stimulation sequence (see col. 4, lines 40-43).

16. Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

17. Regarding Claim 13, Kieval discloses that the cardiac stimulation sequence comprises data based at least in pad on the lowest estimated pulmonary artery diastolic pressure measured during collection of the hemodynamic data (see col. 3, lines 53-57).

18. Regarding Claim 14, see rejection of similarly worded Claim 5 above. As to a computer readable medium, Kieval discloses some type of instructions for performing

this optimization method (see microcomputer 302 in Kieval, col. 9, line 64- col. 10, line 32).

19. Claims 4 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176) in view of Carlson (US Patent 6,026,324).

20. Regarding Claim 4, see rejection of similarly worded Claim 2 above. As to the activity level measurement means, Kieval discloses an activity sensor 316 optionally coupled to the IPG housing (see col. 10, line 36), thereby coupled to the patient, said activity-level measurement means is derived from a piezoelectric crystal transducer (see col. 10, line 38). Kieval and Bornzin do not disclose that the output signal of said activity-level measurement means is time-synchronized to the hemodynamic monitor means. Carlson discloses that the activity-level output and the hemodynamic monitor output signals in a time-synchronized fashion (see col. 7, lines 10-12). The examiner considers that the activity level measurement means accelerometer 50) must output a signal at the same time the hemodynamic monitor (accelerometer 16) outputs a signal to the microprocessor if the level of physical activity is to be a portion of the hemodynamic signal. It would be obvious to one of ordinary skill in the art at the time of the invention to synchronize the output of the activity level measurement means to the hemodynamic monitor means so the activity level can be easily correlated to the hemodynamic status of the heart and an appropriate AV delay can be determined (see col. 7, lines 10-34).

21. Regarding Claim 9, Kieval and Bornzin do not disclose a bi-ventricular device. The applicant does not disclose any criticality to using a bi-ventricular device over any other type of stimulation/monitoring device. Furthermore, bi-ventricular devices are well known and common in the cardiac therapy art. Not only that, an AV device would work equally as well as a bi-ventricular device. Nevertheless, Carlson teaches that the method of optimizing a pacing regime could apply to a variety of different devices, including a bi-ventricular device (see V-V pacing; col. 2, lines 13-16). It would have been an obvious design choice to one of ordinary skill in the art at the time of the invention to use a bi-ventricular device as long as a physiological parameter could be measured along with the level of physical activity in order to provide an appropriate therapy.

22. Regarding Claim 10, Kieval, Bornzin, and Carlson all disclose a dual-chamber pacing mode (see Kieval, Figure 4 and col. 7, lines 54-55; see Bornzin, col. 4, lines 48-50; see Carlson, col. 3, lines 18-19).

23. Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

24. Regarding Claim 13, Kieval discloses that the cardiac stimulation sequence comprises data based at least in pad on the lowest estimated pulmonary artery diastolic pressure measured during collection of the hemodynamic data (see col. 3, lines 53-57).

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
1/9/07

Robert E. Pezzuto
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